



Attorney Docket No. 1489.1001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:

James E. McGowan, Jr.

Application No.: 09/826,420

Group Art Unit: 1744

Filed: April 5, 2001

Examiner: CHORBAJI, MONZER R

For: MEDICAL ARTICLE STERILIZATION METHOD AND DEVICE

REPLY BRIEF UNDER 37 CFR § 41.41

Commissioner for Patents
Board of Patent Appeals and Interferences
United States Patent and Trademark Office
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the Appellant's earlier filed Notice of Appeal on March 29, 2005, the Appellant appealed the Examiner's December 29, 2004 Office Action finally rejecting claims 1-36. Appellant's Appeal Brief was filed August 19, 2005. The Examiner's Answer was mailed December 9, 2005. Appellant's Reply Brief together with the requisite fees set forth in 37 CFR § 41.20 is submitted herewith.

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Spanning pages 8-12 of the Office Action, the Examiner set fourths various issues, which the Examiner apparently believes to be central points in the Appellant's Brief filed on August 19, 2005. Issues 1 and 2 address whether the inventor's previous patent teaches away from the modification suggested by the Examiner. Issues 3-8 address two of the independent claims, and whether it would have been obvious to combine the inventor's previous patent with a Multivac reference. These issues will be addressed in turn.

ISSUE 1

The Examiner addresses Applicant's arguments regarding column 1, lines 36-45 of U.S. Patent No. 5,749,203 ("the '203 patent") as follows:

It is not believed that the past tense ("thought to be") was used to indicate that the science and/or concept was wrong, but only to indicate that the science and/or concept was used previously, i.e., in the past. Even if the prior concept may have been in error, it does not detract from the fact that other types of pretreatment achieve a better result if only by cumulative effect.

The '203 patent states that ethylene oxide is thought to be more molecularly active. Applicant agrees that this sentence, in isolation, does not indicate that the science and/or concept was wrong. However, when read together with the other portions of the reference, it is clear that the reference teaches preconditioning should not be used. If a reference teaches away from a concept, then one of ordinary skill in the art would not believe that a better result is achieved.

ISSUE 2

The '203 patent indicates that pretreatment takes too much time. The Examiner addresses this point as follows:

With respect to "too much time", it is believed that this is not a negative teaching. Only that those applicants wanted a shorter time period. In achieving this shorter period, they were willing to forgo the advantage of having the pretreatment. Although with the pretreatment one would expect better overall sterilization (if only by cumulative effect) if one was willing to forgo the benefit that flow from the pretreatment step.

It is difficult to understand how the Examiner could believe that "too much time" is not a negative teaching. Certainly, it is not a positive teaching. Moreover, it is not a neutral teaching. The references indicates that "too much" is required. This is a negative teaching.

The Examiner indicates that one would expect to achieve better overall sterilization using pretreatment. The '203 patent proposes an entirely different type of sterilization from the process described in connection with pretreatment. Specifically, the '203 patent describes that a form fill and seal process should be used instead of the chamber sterilization process. There is no suggestion that the chamber sterilization process works better. Perhaps the Examiner is picking and choosing parts of the chamber sterilization process to achieve the claimed invention. It is submitted that such a picking and choosing is improper, especially in view of the clear teaching away from the combination.

ISSUE 3

The Examiner states:

The Multivac reference is a part of a form-fill-and seal device as in the instant application such that insuring that air does not enter into packages by substituting one injection means for another would have been obvious to one having ordinary skill in the art of sterilization.

As described previously, the '203 patent teaches that gas elimination is necessary and important.

ISSUE 4

In the Appellant's Brief, Applicants questioned whether the Examiner is proposing that it would have been obvious to add pins or to use pins instead of a nozzle. The Examiner states:

The Examiner's motivation statement is that it would have been obvious to one having ordinary skill in the art to modify the McGowan reference method and device to include gas injection pins in order to eliminate small cracks between webs of film where air can enter packages along with gas are eliminated (column 1, lines 5-10). The phrase "to including gas

injection pins" means to use the pins instead of the nozzle 446.

Applicant disagrees with the Examiner that it would have been obvious to use gas injection pins. Moreover, the reference makes no mention of any substitution. That is, the reference does not mention that anything, including a nozzle, must be eliminated in order to use the pins described in the reference.

ISSUE 5

The Examiner states:

The Multivac reference recognizes in col.1, lines 5-10, that the presence of small cracks between webs is a problem in the art of designing form-fill-and seal devices that one having ordinary skill in the art would use gas injection pins since the pins are totally inside the sealing die.

The cause-and-effect relationship set forth by the Examiner, namely that having pins totally inside the sealing die eliminates cracks, is an implication on the part of the Examiner.

ISSUE 6

The Examiner states:

The Multivac reference teaches in col.1, lines 13-15, that any number of gas injection pins can be used. This teaching includes a single gas injection pin. Clearly, whether one or multiple gas injection pins are used, having pins that are totally placed inside the sealing die eliminates the crack problem.

The Multivac reference states "pins are located on both sides of [the] die." It therefore appears that the Examiner is incorrect in his assertion that any number of gas injection pins can be used.

ISSUE 7

The Examiner states:

The Multivac reference insures that outside contaminated air does not enter the internal sterile medium of packages and that only flushing gas from a cylinder does. The purpose of the Multivac reference is to maintain sterility of the packaged items.

The Multivac reference has been re-read, and no mention could be found regarding a sterilization process or the entry of contaminated air.

ISSUE 8

The Examiner states:

The Multivac reference was combined with the McGowan reference for preventing contaminated air to enter the internal volume of packages along with intended gases and not for lengthening the time of ethylene oxide gas dissipation step.

Applicant appreciates the Examiner clarification. However, as best understood, the reference does not mention contaminated air.

CONCLUSION

In view of the law and facts stated herein, the Appellant respectfully maintains that the reasoning and the references cited by the Examiner are insufficient to maintain either an anticipation rejection or an obviousness rejection of the claims. Appellant respectfully urges that the rejections are improper. Reversal of the rejections in this appeal is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees required in connection with the filing of the Appeal Brief to our Deposit Account No. 19-3935.

Respectfully submitted,

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